

REMARKS

A. Restriction Requirement

Applicants note that the Restriction Requirement has been finalized, but respectfully request that groups I and V be joined, in that the group V claims also now recite the limitations of the Group I claims with respect to increased MS salts and increased picloram, and a search for group V would thus present no additional burden relative to a search for Group I. Thus, Applicants respectfully request that claims 1-4, 24-26, and 28-30 be reconsidered.

B. Status of the Specification

The Specification has been amended to correct typographic errors in the title and in paragraph [0052]. The Specification has also been amended at paragraph [0052] to remove browser executable code. In view of this, Applicants believe that the objection to the Specification is now moot, and respectfully request that it be withdrawn. Applicants also note that the numbering of paragraphs used in the Remarks below corresponds to that found in U.S. Patent Publication 20030154517, which differs slightly from the numbering of paragraphs in the application as filed electronically.

C. Status of the Claims

Claims 5-23, 27, and 31 have been withdrawn in view of the Restriction Requirement. Claims 1 and 24 have been amended to more clearly claim the Applicants' invention. Support for the amendment may be found in the Specification, for instance at paragraph 15. No new matter is added by the amendments, and no subject matter is disclaimed as a result of these amendments. Claims 1-4, 24-26, and 28-30 are currently pending and presented for reconsideration.

D. Claim Rejections Under 35 U.S.C. § 112, First Paragraph

The Action rejects claims 1-3 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

In particular, it is alleged that evaluating all monocotyledonous plants for transformation efficiencies with the media concentrations disclosed would require undue experimentation. In response, Applicants initially note that the current claims are directed to methods for using specific media formulations comprising increased salt and picloram concentrations. In addition, the Potrykus reference cited in the Action no longer reflects the state of the art at the priority date of August 22, 2001, but instead, having been published in 1990, reflects only the state of the art as of that time. Indeed, regarding the alleged “recalcitrance” of monocots to transformation (*e.g.* Action, page 3, bottom), the cited Hansen (1999) reference clearly describes numerous advances in methods for plant transformation, stating for instance that “...many crops, previously classified as recalcitrant...have now been transformed...” (page 226, right column, top paragraph).

Thus, *Agrobacterium*-mediated methods for transformation of corn, rice, barley, and wheat were known in the art as of the priority date of the present application, August 22, 2001. For instance, at least regarding barley (WO99/04618; Tingay *et al.*, 1997. *Agrobacterium tumefaciens*-mediated barley transformation. *The Plant Journal* 11, 1369-1376), rice (*e.g.* U.S. Patent 5,591,616; Raineri *et al.*, 1990. *Agrobacterium*-mediated transformation of rice (*Oryza sativa* L.). *Biotechnology* 8, 33-38; Hiei *et al.*, 1994. *The Plant Journal* 6, 271-282), corn (*e.g.* U.S. Patent 5,591,616; Ishida *et al.*, 1996. High efficiency transformation of maize (*Zea mays* L.) mediated by *Agrobacterium tumefaciens*. *Nature Biotechnology* 14, 745-750), and wheat (*e.g.* WO97/048814; WO00/034491; Cheng *et al.*, 1997. Genetic transformation of wheat mediated by *Agrobacterium tumefaciens*. *Plant Physiology* 115, 971-980, as cited in the Action),

Agrobacterium-mediated transformation methods had been established. Further regarding the Hansen reference, Applicants submit that this reference would instead be understood by one of skill in the art to show, as of 1999, that numerous methods were indeed available for plant transformation, including monocot transformation.

The Action, at page 3, further quotes from two paragraphs on page 228 of the Hansen reference. Applicants respectfully note that these paragraphs relate specifically to dicot transformation, and that, in particular, the “hypersensitive” necrotic reaction is not routinely seen between *Agrobacterium* and monocots such as corn. Instead, it is well known in the art that *Agrobacterium* strains may be successfully used to transform monocot cells such as corn, rice, and wheat, for instance by inclusion of an effective amount of the inducer acetosyringone during the process.

Additionally, even if accepting for the sake of the argument that “optimization” of transformation is species specific as asserted in the Action, Applicants respectfully submit that the specification does not utilize the term “optimized” to describe the claimed methods, and the claims nowhere recite that the transformation method has been “optimized”. Instead, the Specification clearly indicates that “optimization” of media and transfer requirements may be (routinely) implemented for any particular target crop or variety (e.g. paragraphs 33 and 48). Such implementation of the many steps involved in plant cell transformation and regeneration is however not being claimed. The present claims instead relate to transformation efficiency due to the specific described alterations in media and culture conditions, e.g. increased MS salt and picloram levels. Thus, given the detailed teaching in the specification and knowledge of methods for monocot transformation, and in particular for transformation of corn, rice, barley, or wheat, it would require only routine experimentation to determine that the described MS salt and

picloram levels serve to improve the transformation efficiency for that monocot. Applicants thus respectfully request that the rejection be withdrawn.

E. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for use of the term “about”. Applicants respectfully traverse. As an initial matter, it appears unclear why claim 3 would be included in this rejection, apart from being dependent on a rejected claim, as an MS salt concentration is specified in this claim. Further, as noted in the MPEP (2173.05(b)), the term “about” has been held to be clear, but flexible (*Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968; *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)). The term is being used in its ordinary meaning, for instance as found in the Merriam-Webster online dictionary (<http://www.m-w.com/cgi-bin/dictionary>):

about

Function: *adverb*

1 a : reasonably close to <about a year ago>.

The present Specification, gives clear examples understanding the range(s) covered by the term “about.” For instance at paragraph [0032], the Specification states: “The amount of MS salts can be increased from about 1.5- to 3-fold, or for example 2-fold. The amount of picloram can be increased to from about 3 mg/L to 5 mg/L, or for example to about 4 mg/L” (emphasis added). Example 3 (paragraphs [0057-0059]) clearly indicates that levels of MS salts and picloram may be increased in the described M7 medium above the levels found in CM4C. Additionally, claim 1 explicitly recites “...first medium containing increased MS salts...” (emphasis added). The term “increase(d),” being used in its plain and ordinary meaning, also clearly indicates that the claimed range does not read on standard conditions (*e.g.* the level of MS salts typically found in medium CM4C), or reduced salt conditions (or picloram concentrations),

in spite of the assertion in the Action. Applicants thus respectfully request that the rejection be withdrawn.

F. Claim Rejection Under 35 U.S.C. § 103(a)

Claims 1-4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cheng *et al.* (1997) in view of Barro *et al.* (1999). Applicants respectfully traverse. As an initial matter, and for the reasons stated above (Remarks, section “E”), Applicants disagree with the assertion that “For examination purposes the language ‘about 1.5’ is interpreted to read on 1.0 or even amounts less than 1.0”, found in the Action at page 6. As noted above, since claim 1 recites “increased MS salt”, and the term “increased” is being used in its plain and ordinary meaning, increased levels of, for instance, MS salt, can not properly be understood to read on standard or reduced levels. Further, Cheng *et al.*, at page 972, left column, top paragraph, explicitly state that “The MS salts...in the CM4C medium were adjusted to full strength (the original amounts) or one-tenth-strength...”. Nowhere in Cheng is an increased CM4C salt level described (*i.e.* to the level found in M7 medium), nor is there described any effect of such a level on transformation efficiency.

The Action also asserts that Cheng teaches: “The salt strength in the inoculation medium was also found to influence the T-DNA delivery” (page 973, right column, 2nd to last paragraph). However, Applicants note that this statement is made in the context of reduced MS salt concentration in transient GUS expression experiments carried out on freshly isolated embryos, as shown in the next sentence at page 973. The present claims explicitly relate to conditions for preculture of embryos, and an effect of reduced salt concentration on transient transgene expression from freshly isolated immature embryos is not what was being measured to give “transformation efficiency” of precultured embryos in the present application. One of skill in the

art would also understand that transient gene expression does not directly correlate with improved transformation efficiency. This is because, following DNA delivery, a transgene must further be retained, incorporated into the genome, and stably expressed in a regenerated plant in order for such transformation efficiency to be determined. Thus, any effect of salt concentration noted by Cheng is in the context of very different experimental conditions, and clearly is not related to the methods of preculture of embryos that are being claimed. For the reasons noted above, the Cheng reference does not teach all of the limitations of claim 1, and Applicants respectfully submit that addition of the Barro reference does not cure this defect. Withdrawal of the rejection is respectfully requested.

The Action further asserts that, should the claims be interpreted such that the method requires an increase in the MS salt concentration in the preculturing of the immature embryos to double standard strength, it would have further been obvious to modify the method described by Cheng by increasing the concentration of MS salts as suggested by Cheng (sic; see below), considering that the salt concentration was shown to affect the transformation efficiency by Cheng. In response Applicants respectfully traverse, in that it would not have been obvious to modify the method described by Cheng as allegedly suggested by Cheng, given that Cheng teaches alterations (more specifically reduction) in salt content as affecting transient gene expression of freshly isolated embryos, while the present claims relate to stable transformation of precultured embryos. Given these differences in the described experimental conditions, one of skill in the art would not have found it obvious to combine these alleged teachings. In fact, Cheng simply does not provide any teaching on increasing the concentration of MS salts, let alone during preculture of embryos. As Cheng does not teach or suggest all of the limitations of

the present claims, and this defect is not cured by Barro *et al*, Applicants respectfully request that the rejection be withdrawn.

G. Conclusion

In view of the above, it is submitted that the rejections to the claims have been overcome, and the case is in condition for allowance.

The Examiner is invited to contact the undersigned attorney at (512) 536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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